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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,581	01/18/2002	Syed Riauddin Hashmi	455.1005	6351
23280	7590	05/06/2004	EXAMINER	
DAVIDSON, DAVIDSON & KAPPEL, LLC 485 SEVENTH AVENUE, 14TH FLOOR NEW YORK, NY 10018			WELLS, LAUREN Q	
			ART UNIT	PAPER NUMBER
			1617	
DATE MAILED: 05/06/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/031,581	HASHMI ET AL.
	Examiner	Art Unit
	Lauren Q Wells	1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 17 December 2003.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-19 and 22-34 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-19, 22-34 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____.
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____.

### **DETAILED ACTION**

Claims 1-19, 22-34 are pending. The Amendment filed 12/17/03, amended claims 1, 2, 5-7, 12, 14-16, 18, 22, 26-27, 30-34.

The deletion of pages 23-24 of the specification in the Amendment filed 12/17/03 is sufficient to overcome the objection to these pages in the previous Office Action.

Regarding the objection to the improper use of trademarks in the specification, Applicant argues, “in all but isolated instances Applicants’ use of these marks in the specification is consistent with proper trademark usage”. This argument is not persuasive, as the objection applies to “isolated instances”. Thus, this objection is maintained.

The Amendment to claim 22 filed 12/17/03, wherein the method is limited to inflammation, degenerative joints, cartilaginous degeneration, and gastrointestinal sensitivity or irritation, is sufficient to overcome the 35 USC 112, 1<sup>st</sup> paragraph, rejection over this claim in the previous Office Action.

Applicant’s amendments to the claims filed 12/17/03 is sufficient to overcome the 35 USC 112, 2<sup>nd</sup> paragraph rejections, in the previous Office Action.

#### ***103 Rejection Maintained***

The rejection of claims 1-5, 10, 13, 14-19, 22, 24, 28, 31-34 under 35 U.S.C. 103(a) as being unpatentable over Croft (GB 2347349) in view of Dupont et al. (6,028,118) is MAINTAINED for the reasons set forth in the Office Action mailed 7/14/03, and those found below.

The rejection of claims 12, 26, 27, 29 30 under 35 U.S.C. 103(a) as being unpatentable over Croft (GB 2347349) in view of Dupont et al. (6,028,118), as applied to claims 1-5, 10, 13,

14-19, 22, 24, 28, 31-34 above, and further in view of Henderson et al. (6,255,295) is MAINTAINED for the reasons set forth in the Office Action mailed 7/14/03, and those found below.

The rejection of claims 9 and 23 under 35 U.S.C. 103(a) as being unpatentable over Croft (GB 2347349) in view of Dupont et al. (6,028,118), as applied to claims 1-5, 10, 13, 14-19, 22, 24, 28, 31-34 above, and further in view of Church (Velvet Antler: It's Historical Medical Use) is MAINTAINED for the reasons set forth in the Office Action mailed 7/14/03, and those found below.

The rejection of claims 7, 8 and 25 under 35 U.S.C. 103(a) as being unpatentable over Croft (GB 2347349) in view of Dupont et al. (6,028,118), as applied to claims 1-5, 10, 13, 14-19, 22, 24, 28, 31-34 above, and further in view of Burger (5,843,919) is MAINTAINED for the reasons set forth in the Office Action mailed 7/14/03, and those found below.

The rejection of claim 11 under 35 U.S.C. 103(a) as being unpatentable over Croft (GB 2347349) in view of Dupont et al. (6,028,118), as applied to claims 1-5, 10, 13, 14-19, 22, 24, 28, 31-34 above, and further in view of Kosuge et al. (4,801,453) is MAINTAINED for the reasons set forth in the Office Action mailed 7/14/03, and those found below.

Applicant argues, “the combination of these elements provides a synergistic effect that is not found, and that would not be thought to exist, with any of the elements individually. Although similar compounds are present, it is likely that the improved effect of the composition of the present invention over either of the two ingredients when utilized alone is due to the efficacy enhancing nature of compounds other than glycosaminoglycans present in the shark cartilage”. This argument is not persuasive, as it is not commensurate in scope with the instant

claims. The instant claims are directed to a composition and methods of use. It is respectfully pointed out that Applicant has not provided any unexpected results of synergy over the closest prior art. Thus, this argument is not persuasive.

Applicant argues, “Whereas both Dupont et al. and Croft mention treatment of inflammatory conditions, a great many other pharmaceutical compositions also exist to treat inflammation, and there is nothing in the prior art that even suggests that it may be useful to include shark cartilage within the composition of Croft in order to enhance the actions of green-lipped mussel extract therein”. This argument is not persuasive. First, this argument is not commensurate in scope with the instant composition claims, as the intended use of the composition claims is not given patentable weight in the instant claims. Second, there is motivation to combine shark cartilage and green-lipped mussel extract, as outlined in the previous Office Action. While the motivation may not be what Applicant envisions, i.e., enhancing the effects of a green lipped mussel extract, there is still motivation to combine them—it is obvious to combine two compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose (In re Kerkoven, 205 USPQ 1069 (CCPA 1980)), and because of the expectation of enhancing blood flow to the suffering area. Third, while Dupont and Croft may teach the treatment of inflammatory conditions along with other conditions, that does not discount the fact that they teach the treatment of inflammatory conditions. A teaching is a teaching. The Examiner respectfully points out that this is a 103-obviousness type rejection and not a 102 anticipation rejections.

Applicant argues, “there is nothing in the prior art that even suggest that is may be useful to include bark extract in order to enhance the actions of either green-lipped mussel extract or shark cartilage. This lack of suggestion is because shark cartilage and green-lipped mussel extract contain the same active ingredients, and one would not be motivated to combine two remotely derived substances that have the same active ingredients”. This argument is not persuasive. This argument is not commensurate in scope with the instant claims. As the instant independent claims contain two Markush groups, bark extract is not necessary to meet the instant claims.

Applicant argues, “Dupont does not teach the nature of the active component in shark cartilage but states throughout that the anti-collagenolytic factor present is of less than 10kDa, which means that it is not likely to be glycosaminoglycans. Perhaps the factors of lighter molecular weight augment the activity of the GLME to a greater extent than they do the glycosaminoglycans present when bound in cartilage, hence the greater anti-inflammatory activity of the combination”. This argument is not persuasive. Again, the argument is not commensurate in scope with the instant claims. The instant claims recited “shark cartilage”. Thus, a teaching of “shark cartilage” meets the limitation. Furthermore, it is respectfully pointed out that a compound and its properties are inseparable. Thus, while Dupont may not state all the properties of the shark cartilage, the properties are inherent to the shark cartilage.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 6, 15-19, 22, are rejected under 35 U.S.C. 103(a) as being unpatentable over Croft (GB 2347349) in view of Bath et al. (6,333,304).

Croft teaches a synergistic composition comprising green-lipped mussel extract and glycosaminoglycan for treating osteoarthritis or rheumatoid arthritis. The glycosaminoglycan can be in the form of chondroitin sulphate. The composition may be administered in capsule or tablet form, i.e., oral administration. Taught is a method of treating inflammation in a non-human animal. The reference lacks an enhancing agent. See abstract; pages 2-4; 7-8.

Bath et al. teach treatments for arthritis in animals, including non-human animals. Pine bark extract is taught as scavenging free radicals, inhibiting mast cell degranulation (cause of inflammatory response), reducing histamine release (cause of inflammatory response), and inhibiting enzymes that break down collagen and elastin, thereby stopping the deterioration of joints, and quelling inflammation. See Col. 8, lines 13-26; Col. 5, lines 24-40.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the pine bark extract of Bath et al. to the composition of Croft because it is obvious to combine two compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose. *In re Kerkoven*, 205 USPQ 1069 (CCPA 1980). Additionally, it would have been obvious to add the pine bark extract of Bath et al. to the composition of Croft because of the expectation of stopping the deterioration of the joint, quelling inflammation, and stopping free radical damage.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

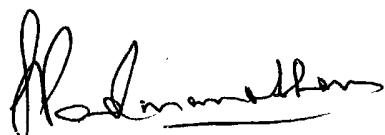
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is 571-272-0634. The examiner can normally be reached on M&R (5:30-4).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

lqw



SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER